

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ )  
FENFLURAMINE/DEXFENFLURAMINE) MDL NO. 1203  
PRODUCTS LIABILITY LITIGATION )  
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THIS DOCUMENT RELATES TO: )  
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SHEILA BROWN, et al. ) CIVIL ACTION NO. 99-20593  
 )  
v. )  
 )  
AMERICAN HOME PRODUCTS ) 2:16 MD 1203  
CORPORATION )

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9110

Bartle, J.

July 10, 2013

The Estate of Charlene Majurski ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Brian D. Majurski ("Mr. Majurski"), Charlene Majurski's ("Ms. Majurski" or "decedent") spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify Diet Drug

(continued...)

To seek Matrix Benefits, a representative claimant<sup>4</sup> must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the Diet Drug Recipient's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In February, 2005, Mr. Majurski, personal representative of Ms. Majurski's estate, submitted a supplemental Green Form to the Trust signed by decedent's attesting physician, Vincent A. Gaudiani, M.D. Based on an echocardiogram dated

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3. (...continued)

Recipients for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients were diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators, or other legal representatives, heirs or beneficiaries. See Settlement Agreement § II.B.

August 25, 2004, Dr. Gaudiani attested in Part II of the Green Form that Ms. Majurski suffered from moderate mitral regurgitation and moderate aortic regurgitation and that she died as a result of a condition caused by VHD or valvular repair/replacement surgery.<sup>5</sup> Based on such findings, the Estate would be entitled to Matrix A-1, Level V benefits<sup>6</sup> in the amount of \$572,449.<sup>7</sup>

Dr. Gaudiani also attested that Ms. Majurski was not diagnosed with Systemic Lupus Erythematosus and valvular abnormalities of a type associated with this condition. Under the Settlement Agreement, a diagnosis of Systemic Lupus Erythematosus and valvular abnormalities of a type associated

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5. In addition, Dr. Gaudiani attested that Ms. Majurski suffered from an abnormal left ventricular end-systolic dimension greater than or equal to 45 mm by M-mode or 2-D Echocardiogram, a reduced ejection fraction in the range of 40% to 49%, and New York Heart Association Functional Class II symptoms. Dr. Gaudiani also attested that Ms. Majurski underwent surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a representative claimant is entitled to Level V benefits if the Diet Drug Recipient suffered "[d]eath resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred post-Pondimin® and/or Redux™ use supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records[.]" See Settlement Agreement § IV.B.2.c.(5)(c).

7. Ms. Majurski previously was paid Matrix A-1, Level II benefits in the amount of \$473,032. According to the Trust, if entitled to Matrix A-1, Level V benefits, the Estate would be entitled to Matrix Benefits in the amount of \$1,045,481. The amount at issue, therefore, is the difference between the Matrix A-1, Level II benefits already paid and the amount of Matrix A-1, Level V benefits.

with this condition requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)iii)d). As the Trust does not contest the Estate's entitlement to Level V benefits, the only issue before us is whether the Estate is entitled to payment on Matrix A-1 or Matrix B-1.<sup>8</sup>

In April, 2005, the Trust forwarded the claim for review by Donna R. Zwas, M.D., F.A.C.C., one of its auditing cardiologists.<sup>9</sup> In audit, Dr. Zwas concluded that there was no reasonable medical basis for Dr. Gaudiani's finding that Ms. Majurski did not have Systemic Lupus Erythematosus and valvular abnormalities of a type associated with this condition. Specifically, Dr. Zwas explained that:

The surgeon describes "small excrescences on the underside of the leaflet," and the pathologist finds there to be "a small amount of fibrin adherent to the surface of the valve[.] ..." Fibrin deposition on the underside of the valve leaflets is a classic manifestation of Libman-Sacks valve lesions, which are found in systemic lupus erythematosus. The findings of mild thickening on the echocardiograms are not specific for the changes in lupus.

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8. If the Estate's supplemental claim for Level V benefits is payable only on Matrix B-1, the Estate will not receive any additional Matrix Benefits because the amount to which the Estate would be entitled is less than the amount Ms. Majurski previously received for her Matrix A-1, Level II claim.

9. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims were subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that the Estate had a Matrix A-1, Level V claim, the Trust audited the Estate's claim pursuant to the PPP.

Based on the auditing cardiologist's finding that Ms. Majurski had Systemic Lupus Erythematosus and valvular abnormalities of a type associated with this condition, the Trust issued a post-audit determination that the Estate was entitled only to Matrix B-1, Level V benefits. Pursuant to the Rules for Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.<sup>10</sup> In contest, the Estate argued that it should prevail because "the best evidence establishes that Pondimin damage - not lupus - destroyed Ms. Majurski [sic] heart valves and killed her." In support, the Estate submitted a letter from Stephen Raskin, M.D., F.A.C.C., the attesting physician for Ms. Majurski's initial claim for Matrix Benefits. In his letter, Dr. Raskin concluded that "based on my review of the medical evidence and pertinent literature, it is most likely that Ms. Majurski's VHD was the result of her exposure to diet drugs."

The Trust then issued a final post-audit determination, again determining that the Estate was entitled only to Matrix B-1, Level V benefits. The Estate disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See

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10. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c).

The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On November 8, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5841 (Nov. 8, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on February 24, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>11</sup> to review claims after the Trust and the Estate have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and the Estate and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether the Estate has met its burden of proving that there is a

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11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to aid it in resolving technical issues. Id.

reasonable medical basis for the attesting physician's finding that Ms. Majurski did not have Systemic Lupus Erythematosus and valvular abnormalities of a type associated with this condition. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in the Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of its claim, the Estate argues it should prevail because the diagnosis of Systemic Lupus Erythematosus in Ms. Majurski's medical records was erroneous. It relied on Dr. Raskin's declaration, wherein he stated:

The available record review, on the contrary, reveals non-specific pathological findings which are distinctly atypical for descriptions of [Systemic Lupus Erythematosus] related VHD. The gross aortic valve pathology described in Dr. Vincent Gaudiani's operative report as "small excrescences on the underside [or ventricular aspect] of the [aortic] leaflets" and his description of the mitral valve that revealed "a satisfactory valve" with [only] mitral annular dilation are not typical of [Systemic Lupus Erythematosus] associated valvulopathy.

The Estate asserts that the diagnosis of Systemic Lupus Erythematosus is incorrect because Ms. Majurski only displayed cutaneous symptoms, indicative of discoid lupus. In addition, the Estate contends that valve thickening indicative of lupus

valvulopathy is not present in Ms. Majurski's case. Finally, the Estate argues that the auditing cardiologist inappropriately determined that Ms. Majurski had Systemic Lupus Erythematosus based on a finding of Libman-Sacks endocarditis, which cannot be inferred from gross anatomical findings.

In response, the Trust argues that Dr. Raskin's opinion that Ms. Majurski did not have Systemic Lupus Erythematosus is irreconcilable with Ms. Majurski's medical records. In particular, the Trust notes that Dr. Sigal Tene examined Ms. Majurski weeks before she died and determined that "although her lupus may have initially presented as discoid lupus involving the skin, her lupus developed into systemic lupus erythematosus with significant joint involvement, photosensitivity, elevated antinuclear antibody, and rheumatoid factor." The Trust also contends that the Estate seeks to impose a causation requirement regarding the reduction factor of Systemic Lupus Erythematosus that is inconsistent with the plain language of the Settlement Agreement.

The Technical Advisor, Dr. Vigilante, reviewed Ms. Majurski's medical records and concluded that there was no reasonable medical basis for Dr. Gaudiani's finding that she did not have Systemic Lupus Erythematosus and valvular abnormalities of a type associated with this condition. In particular, Dr. Vigilante determined that:

... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question[] E.8. As noted above, there

is irrefutable evidence from the medical records that the claimant had Systematic Lupus Erythematosus. This was documented by several health care providers. There were noted to be skin changes, arthritic abnormalities, and serologic evidence of [Systemic Lupus Erythematosus] with a positive antinuclear antibody. In addition, at the time of surgery, Dr. Gaudiani noted an abnormal aortic valve with small excrescences and he wondered if these were related to lupus. Dr. Valentino believed that the pathologic evaluation of the aortic valve could be a manifestation of the Claimant's underlying lupus. The valvular abnormalities noted on the echocardiograms, at the time of surgery and on pathologic exam have been associated with [Systemic Lupus Erythematosus]. Therefore, the Claimant did have a diagnosis of [Systemic Lupus Erythematosus] and had valvular abnormalities of a type associated with Systematic Lupus Erythematosus.

In response to the Technical Advisor Report, the Estate argues that Ms. Majurski did not have Systemic Lupus Erythematosus, which requires an affirmative finding as to at least four of eighteen features of the disease. In addition, the Estate contends that Dr. Vigilante either mischaracterizes or ignores certain parts of Ms. Majurski's medical records.

After reviewing the entire Show Cause Record, we find the Estate's arguments are without merit. The Settlement Agreement specifically provides that a claimant will receive reduced Matrix Benefits if there is evidence of a specific medical condition, including a diagnosis of Systemic Lupus Erythematosus and valvular abnormalities of a type associated with this condition. See Settlement Agreement § IV.B.2.d.(2)(c)iii)d).

Ms. Majurski's medical records repeatedly reflect that she was diagnosed with Systemic Lupus Erythematosus. For example, an April 29, 1999 Cardiac Ultrasound Report noted that "Ms. Majurski is a 56 year old white female with history of cardiomyopathy and lupus erythematosus."<sup>12</sup> Similarly, a Pulmonary Consultation Report noted "[t]he patient is known to have systemic lupus erythematosus, manifesting with skin eruption (discord lupus, as well as photosensitivity)." An August, 2004 Consultation Report also notes that "[t]he patient is a very pleasant, 61 year old female who carries the diagnosis of lupus," and that "[l]upus was diagnosed seven to eight years ago." In addition, Ms. Majurski's August 20, 2004 Operative Report for her aortic and mitral valve surgery reflects that both the preoperative and postoperative diagnoses included "Lupus erythematosus." The same Operative Report notes that Ms. Majurski "has long-standing lupus." The Final Summary for Ms. Majurski's hospitalization also listed, as one of the "Secondary Diagnoses," systemic lupus.

Following Ms. Majurski's valve surgery, her aortic valve was examined by Leonard A. Valentino, M.D. In the Surgical Pathology Report for Ms. Majurski's aortic valve, Dr. Valentino noted, in relevant part, the following:

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12. An April 1, 1998 echocardiogram report also noted, under clinical information, that Ms. Majurski had "Hx lupus erythematosus."

CLINICAL INFORMATION: [Aortic valve replacement] -MVV. Patient has lupus - what is on the valve?

....

COMMENT: A small amount of fibrin is adherent to the surface of the valve. This is sometimes present in association with small numbers of lymphocytes close to the surface of the valve. The changes are quite mild and not specific, but could be a manifestation of the patient's underlying lupus.

Finally, in Ms. Majurski's Death Certificate, the attesting physician, Dr. Gaudiani, certified, under the category of "Other Significant Conditions Contributing to Death," Systemic Lupus Erythematosus.

In addition, Dr. Vigilante confirmed after his review that "there is irrefutable evidence from the medical records that the claimant had Systemic Lupus Erythematosus." Dr. Vigilante specifically noted that "[t]he valvular abnormalities noted on the echocardiograms, at the time of surgery and on pathologic exam have been associated with [Systemic Lupus Erythematosus]."

Although the Estate submitted the declaration of Dr. Raskin wherein he asserted that Ms. Majurski either never received a positive diagnosis of Systemic Lupus Erythematosus or was misdiagnosed with Systemic Lupus Erythematosus, the Estate did not obtain a statement from any of Ms. Majurski's treating physicians to explain why they concluded she suffered from Systemic Lupus Erythematosus. Based on Ms. Majurski's medical records, we reject the Estate's argument that Ms. Majurski did

not have Systemic Lupus Erythematosus and valvular abnormalities of a type associated with this condition.<sup>13</sup>

We further disagree with the Estate's argument that it is entitled to Matrix A benefits because Ms. Majurski's VHD was due to her ingestion of Diet Drugs rather than Systemic Lupus Erythematosus. Causation is not at issue in resolving the Estate's claim for Matrix Benefits. Rather, the Estate is required to show that it meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which the qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true, namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the condition at issue. The Settlement Agreement clearly and unequivocally requires a

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13. We also reject the Estate's argument that Dr. Vigilante did not properly consider Ms. Majurski's medical records.

claim to be reduced to Matrix B-1 if there is a diagnosis of Systemic Lupus Erythematosus and valvular abnormalities of a type associated with this condition. See Settlement Agreement § IV.B.2.d.(2)(c)iii)d). We must apply the Settlement Agreement as written. Accordingly, the Estate's assertion that the cause of Ms. Majurski's valvular heart disease was her ingestion of Diet Drugs is irrelevant to the issue before the court. As Ms. Majurski had a diagnosis of Systemic Lupus Erythematosus, the Settlement Agreement requires that the Estate's claim be reduced to Matrix B-1.

For the foregoing reasons, we conclude that the Estate has not met its burden of proving that there is a reasonable medical basis for finding that Ms. Majurski was not diagnosed with Systemic Lupus Erythematosus and valvular abnormalities of a type associated with this condition as set forth in the Settlement Agreement. Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix A-1, Level V Benefits and the related derivative claim submitted by Ms. Majurski's spouse.